IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

GAYNELL GRIER, et al., individually and on behalf of others similarly situated,	)	
Plaintiffs,	)	
v.	)	Case No. 3:79-3107
	)	Judge Nixon
M.D. GOETZ, JR., Commissioner, Tennessee Department of Finance and Administration, et al.,	)	Class Action
Defendants,	)	
and	)	
TENNESSEE ASSOCIATION OF HEALTH MAINTENANCE ORGANIZATIONS, et al.,	)	
Defendants-Intervenors.	)	
SANFORD BLOCH, MARK LEVINE, TIM JONES, and WILLIAM DUNCAN, and MARY KATHRYN DUNCAN, by their next friend, ROBERT DUNCAN,	)	
Plaintiffs-Intervenors.	)	

REVISED ORDER

After consideration of the testimony adduced during the hearings that took place between June 29, 2005 and July 19, 2005; the parties Proposed Findings of Fact and Conclusions of Law (Doc. Nos. 1237, 1238, 1239, 1241, 1240); and upon hearing closing arguments on July 28, 2005, the Court **GRANTED in part** and **DENIED in part** Defendants' Motion to Modify and/or Clarify the Consent Decree (Doc. Nos. 1086, 1087) by order entered July 29, 2005 (Doc.

No. 1248). On August 1, 2005, Defendants requested clarification of certain paragraphs of the Court's July 29, 2005 Order, to which Plaintiffs responded (Doc. No. 1250).

In balancing the time-sensitive nature of this case with the intricacies of Defendants' requests, the Court issued piecemeal orders, which understandably now need further clarification. Nevertheless, after considering Defendants' requests for clarification, Plaintiffs' responses, and argument heard on August 1, 2005 and August 2, 2005, the Court notes that the Defendants' clarification requests primarily entail implementation of the Court's broader rulings on July 28, 2005, and July 29, 2005. Based on their collective hands-on experience with the case, their numbers, and their legal talent, the parties' attorneys are well-equipped to find practical solutions to the Court's rulings, and the Court is disappointed in the lack of communication between them and the resulting failure to fashion such solutions. Additionally, it must be noted that the Defendants now have received sufficient direction from this Court to determine whether they can implement their large-scale reforms or embrace the Memorandum of Understanding; further clarification of details and practical solutions relating primarily to the appeals process need not detain the Defendants in that endeavor.

After due consideration, the Court hereby clarifies its previous Orders, and this August 3, 2005 Revised Order incorporates and supercedes the July 28, 2005 and July 29, 2005 Orders.

The Court finds that there is significant change in the circumstances to warrant modification of the 2003 Revised Consent Decree (Modified). See Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367 (1992); Fed. R. Civ. P. 60(b). The Court also finds that certain modifications are suitably tailored to the changed circumstances, while others are not. Id. Accordingly, the Court hereby **ORDERS** that:

(i) Defendants' Request (a) regarding the implementation of all reforms approved by the Centers for Medicare and Medicaid Services ("CMS"), is **GRANTED in part** and **DENIED in part**. Pursuant to Fed. R. Civ. P. 60(b) and the governing case law, the Court cannot revise the 2003 Revised Consent Decree (Modified) unless the proposed modifications are suitably tailored to rectify the circumstances that warrant modification. See Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367 (1992); Fed. R. Civ. P. 60(b). Similarly, the proposed modifications must fall within constitutional requirements. Id. The Court cannot conduct this analysis on future reforms that the State has not yet articulated to this Court. Accordingly, the State may implement the reforms already approved by CMS in its letters to the State dated March 24, 2005 and June 8, 2005, subject to this Court's ruling as set forth below. Defendants' Request (a) regarding implementation of future reforms not yet approved by CMS is **DENIED**. Notwithstanding this ruling, the State need not seek Court approval for future changes to the TennCare program that are approved by CMS unless such changes are inconsistent with the 2003 Revised Consent Decree (Modified), as revised by this Order. This ruling does not alter the requirements of Section D of the 2003 Revised Consent Decree (Modified);

(ii) Defendants' Request (b) regarding prior authorization is **GRANTED in part** and **DENIED in part**. The State may require prior authorization by the TennCare Bureau as a condition of coverage for any drug or drug class so designated by the State. The Court finds that categorical denial of a claim for reimbursement for a drug for which prior authorization is required, but has not been obtained, is not suitably tailored to the circumstances. Accordingly, the State may not deny reimbursement for a 72-hour emergency supply of a drug for which prior authorization is required, but has not been obtained, in accordance with the Court's ruling in

subparagraph (vii) of this Order. Similarly, the State may not categorically deny a claim for reimbursement from an enrollee. Upon receiving an enrollee's request for reimbursement for a drug for which prior authorization is required, but has not been obtained, the State must conduct the same prior authorization process or analysis it would have conducted prior to the dispensing of the drug. In the event the prior authorization would have been granted, the enrollee shall be reimbursed. In the event the prior authorization would have been denied, the enrollee's request for reimbursement shall be denied, at which point the enrollee may appeal the State's decision to deny authorization of the drug consistent with subparagraph (iv) of this Order. This ruling does not extend to claims for reimbursement by providers and pharmacists, and the State may deny any claim for reimbursement by providers and pharmacists for a drug for which prior authorization is required, but has not been obtained;

(iii) Defendants' Request (c) regarding the five prescription per month limit is **GRANTED** with the Court's recommendation and expectation that the State will implement a "soft" five prescription per month limit, as reflected by the State's representation during closing argument on July 28, 2005, and after creating and obtaining CMS approval for an appropriate "soft" limit policy;

(iv) Defendants' Request (d) regarding appeals of denials of authorization for a drug is **GRANTED in part** and **DENIED in part**. Accordingly, the Court hereby orders that:

(1) The State may, when a request for prior authorization of a drug is denied, issue through its Pharmacy Benefit Manager ("PBM") a notice informing the enrollee of the basis for the denial, and that notice may be issued after the service has been denied.

(2) If the enrollee appeals the denial of prior authorization or coverage, the

State will have no obligation to pay for the service during the pendency of any appeal, subject to the following exceptions:

(A) The State shall comply with the 72-hour emergency supply requirements of Paragraph C(14)(a) – (c), as revised by subparagraph (vii) of this Order; the enrollee is entitled under those provisions to a single 72-hour emergency supply while the appeal is pending; or,

(B) The drug in question has been prescribed on an ongoing basis or with unlimited refills (e.g., insulin for the treatment of diabetes), in which case the State or its contractor shall comply with Paragraph C(8) of the 2003 Revised Consent Decree (Modified), which implements 42 C.F.R. §§ 431.230-431.231 requiring maintenance or reinstatement of services pending an appeal in the event of a termination or reduction of services. The denial of prior authorization of a drug that an enrollee is already taking because it is prescribed on an ongoing basis or with unlimited refills constitutes a termination or reduction of coverage of a drug triggering the protections of 42 C.F.R. §§ 431.230-431.231 and Paragraph C(8).

Notwithstanding this ruling, the State or its contractor shall not be bound to comply with Paragraph C(2)(c) of the 2003 Revised Consent Decree (Modified) requiring notice in the event a drug that is prescribed on an ongoing basis or with unlimited refills becomes subject to prior authorization. Paragraph C(2)(c) of the 2003 Revised Consent Decree (Modified) purports to implement 42 C.F.R. §§ 431.206, 431.210-214, which describe when an enrollee must receive notice of the right to a hearing and the contents of such notice. Section 431.206(c)(2) requires the State to provide notice of an enrollee's right to a hearing "[a]t the time of any action affecting his or her claim." An "action" is defined as termination, suspension or reduction of Medicaid eligibility or covered services. See 42 C.F.R. § 431.201. Accordingly, the denial of prior

authorization gives rise to an enrollee's right to a hearing, and triggers the notice requirement. See supra ¶ (iv)(1). The fact that a drug becomes subject to prior authorization, however, does not constitute a termination, suspension or reduction of a covered service and does not trigger the notice requirement.

The Court interprets Paragraph C(2)(c) of the 2003 Revised Consent Decree (Modified) as requiring notice at the time a drug becomes subject to prior authorization, not at the time of denial of prior authorization. While such a prophylactic measure appears reasonable given the likelihood of a busy physician to overlook the fact that a previously written prescription later becomes subject to prior authorization, it can also be an onerous requirement for the State, and undermines the State's reforms to create an effective prior authorization regime. In light of the fact that it is not specifically required by federal law, the State shall not be bound by the notice provisions of Paragraph C(2)(c) of the 2003 Revised Consent Decree (Modified) in the event a drug becomes subject to prior authorization. Paragraph C(2)(c) is binding for all other purposes. The Court nonetheless recommends that the State implement a less onerous prophylactic measure to foster communication between the treating physician and the enrollee to ensure prior authorization is timely received and limit interruptions in refilling prescriptions. For example, the State may require pharmacists to provide a notice to enrollees at the time a prescription is refilled during the "grace period" -- the period during which prior authorization is required for the drug, but the drug is not denied for failure to obtain such authorization -- informing the enrollee to remind the treating physician to obtain prior authorization; or,

(C) The enrollee ultimately prevails on the appeal and is found to have been eligible to have received the services, in which case the State or its contractor shall make

corrective payments, retroactive to the date that the incorrect denial of coverage occurred, as required by 42 C.F.R. § 431.246 and Paragraph C(13) of the 2003 Revised Consent Decree (Modified), as revised by subparagraph (xv) of this Order.

(3) The State action from which an appeal may be taken is the State's denial of requested prior authorization. Such action is included within the definition of an "adverse action" giving rise to the right to appeal under Paragraph B(5) of the 2003 Revised Consent Decree (Modified). Insofar as the State's motion requests a modification to limit appeals to the State's denial of requested prior authorization, it is **DENIED**.

(4) A valid appeal may be taken where no prior authorization has been sought for a drug requiring such authorization in order to be treated as a covered service (and therefore no prior authorization request has been denied). This ruling does not preclude the State, upon receipt of an appeal where no prior authorization has been sought for a drug requiring such authorization, from (a) performing the prior authorization analysis prior to processing the appeal, consistent with subparagraph (ii) of this Order, (b) requiring the enrollee to request his or her treating physician to obtain prior authorization, (c) assisting the enrollee in obtaining access to a physician who can obtain the required prior authorization in the event an enrollee is unable to reach his or her treating physician or does not have access to a physician, or (d) assisting the enrollee in any other manner to obtain the required prior authorization. In accordance with subparagraph (xi) of this Order, the time limitations set forth in Paragraph C(10) shall be tolled in the event the State initiates steps (a), (b), (c) or (d), unless the State does not act with reasonable promptness, in which case, the time limitations set forth in Paragraph C(10) shall restart. See 42 C.F.R. § 431.220(a). The Court recommends that the State, upon consultation with the other parties to this action, create guidelines for what constitutes

"reasonable promptness" in this context;

(5) The State may dismiss without a hearing any appeal of a denial of prior authorization that does not raise a valid factual dispute. See Rosen, et al., v. Goetz, 410 F.3d 919 (6th Cir. 2005);

(v) Defendants' Request (e) regarding the content of a drug formulary and designation of drugs available without prior authorization is **GRANTED**;

(vi) Defendants' Request (f) regarding categorical exclusion of coverage for over-the-counter drugs is **GRANTED** with the Court's recommendation that over-the-counter drugs be excluded on a "soft" basis consistent with this Court's ruling in subparagraph (iii) above;

(vii) Defendants' Request (g) regarding the 72-hour drug supply for drugs requiring prior authorization for which such authorization has not been obtained is **GRANTED** in its entirety with the Court's recommendation that the prior authorization policy be phased in to allow initially a 72-hour interim supply of a prescription drug for which no prior authorization has been obtained, until such time that pharmacists have been provided appropriate guidelines and have received training in how to determine an emergency situation, as defined by the State, at which time the 72-hour supply will be limited to emergency situations. Paragraph C(14)(e) of the 2003 Revised Consent Decree (Modified) shall be deleted;

(viii) Defendants' Request (h) regarding benefit limits is **GRANTED in part** and **DENIED in part.** Accordingly, the Court hereby orders that:

(1) When the State imposes benefit limits capping the number of in-patient hospital days per year, physician services per year, outpatient facility services per year, laboratory

and x-ray services per year, inpatient and outpatient substance abuse services over the course of the enrollee's lifetime, and/or prescriptions per month that will be covered by TennCare, the State may deny any claim for services or reimbursement for services whenever such services would exceed a benefit limit imposed by the State. The Court recommends that the State implement a "soft" benefit limit consistent with this Court's ruling in subparagraph (iii).

(2) When a claim for service or reimbursement is denied by the State or a managed care contractor ("MCC") because the enrollee has reached the benefit limit, the State must issue a notice informing the enrollee of the basis for the denial at the time the claim is denied (which may be after the service has been denied by a provider). Such notice need only be provided the first time an enrollee exceeds a particular benefit limit within a particular time period, and the State or MCC need not issue repeated notices for denials of that same benefit for the remainder of the applicable period. In the event that the State or a MCC issues a notice, but it is later determined that the enrollee had not reached their benefit limit, the State or MCC shall issue a new notice informing the enrollee of the basis for the denial at the time the claim is denied when the person does subsequently reach the benefit limit.

(3) The State need not provide notice that an enrollee is approaching or has exceeded his benefit limit.

(4) A provider's refusal to render a requested service because the enrollee has reached a benefit limit constitutes action by the State, and the State shall provide notice in those circumstances. See Tennessee Ass'n of Health Maint. Orgs., Inc. v. Grier, 262 F.3d 559 (6th Cir. 2001). This ruling does not preclude the State from creating a standard, preprinted notice for

distribution by providers in such situations.

(5) If the enrollee appeals the denial of coverage, the State may refuse to pay for the service while the appeal is pending; provided, however, that if the enrollee ultimately prevails on the appeal, the State or its contractor must take corrective action, as required by 42 C.F.R. § 431.246.

(6) The State may dismiss without a hearing any appeal of a denial based upon a benefit limit that does not raise a valid factual dispute. See Rosen, et al., v. Goetz, 410 F.3d 919 (6th Cir. 2005);

(ix) Defendants' Request (i) regarding co-pays is **GRANTED in part** and **DENIED in part**. Accordingly, the Court hereby orders that:

(1) The State may impose and/or increase the co-pays charged for any TennCare service.

(2) The State may not deny any claim for services for which the co-pay has not been paid.

(3) The State may dismiss without a hearing any appeal of a denial for refusal to pay the co-pay that does not raise a valid factual dispute.

(4) A provider's refusal to provide a requested service because the enrollee did not pay the co-pay constitutes action by the State, and the State shall provide notice in those circumstances. See Tennessee Ass'n of Health Maint. Orgs., Inc. v. Grier, 262 F.3d 559 (6th Cir. 2001). This ruling does not preclude the State from creating a standard, preprinted notice for distribution by providers in such situations;

(x) Defendants' Request (j) regarding appeals of service denials that also raise eligibility category challenges is **GRANTED in part** and **DENIED in part**. The State may refuse to consider, as a ground for an appeal of a service denial, challenges to an enrollee's eligibility category that an enrollee had the opportunity to raise previously unless the enrollee can show excusable neglect for not previously raising the eligibility category challenge. The State may implement an administrative process to determine whether there is excusable neglect preventing a previous challenge to an eligibility category.

(xi) Defendants' Request (k) regarding appeals initiated by an enrollee without a prescription or service is **DENIED**. Notwithstanding this ruling, Paragraph C(10) does not prevent the State from creating an administrative grievance or other informal process to address requests by enrollees without a prescription or a service, including, but not limited to, network access requests. The State may require an enrollee to exhaust this administrative grievance or informal process before the enrollee's appeal can go forward. Accordingly, the time limitations in Paragraph C(10) shall be tolled until the administrative grievance or informal process is completed, provided, however that the administrative grievance or informal process is completed with reasonable promptness. In the event the administrative grievance or informal process is not completed with reasonable promptness, the time limitations in Paragraph C(10) shall restart. See 42 C.F.R. § 431.220(a). The Court recommends that the State, upon consultation with the other parties to this action, create guidelines for what constitutes "reasonable promptness" in this context;

(xii) Defendants' Request (l) is **GRANTED in part** and **DENIED in part** such that the State may rely upon all relevant information, not just the enrollees' medical records, in

determining TennCare coverage of medical services and in considering and deciding medical appeals. Defendants' request to delete Paragraph C(7) of the 2003 Revised Consent Decree (Modified) is **DENIED**. Notwithstanding this ruling, the first sentence of Paragraph C(7)(b) may be revised such that the weight given to the treating physician's opinion shall increase if it is well-supported with evidence from an enrollee's medical records and/or other relevant information. For example, on the one hand, a treating physician's conclusory statements, without more, should not bind the State. On the other hand, the State may not require the treating physician to justify any deviation from the standard course of treatment when the physician's opinion is reasonably supported with evidence from the enrollee's medical records. The State, upon consultation with the other parties to this action, shall submit its proposal for approval of such modification to this Court at a time to be determined by this Court subsequent to the issuance of the Memorandum Order;

(xiii) Defendants' Request (m) regarding a screening process to identify appeals that are not based upon a valid factual dispute is **GRANTED**. See Rosen, et al., v. Goetz, 410 F.3d 919 (6th Cir. 2005);

(xiv) Defendants' Request (n) regarding the burden of proof in medical appeals is **GRANTED** subject to subparagraph (xii) of this Order;

(xv) Defendants' Request (o) to modify Paragraph C(13) of the 2003 Revised Consent Decree (Modified) to permit the State to appeal a medical appeal decision rendered at any stage of the process in favor of the enrollee is **GRANTED**. Notwithstanding this ruling, the State must comply with 42 C.F.R. § 431.246 requiring prompt corrective action in the event of a decision

favorable to the enrollee at any stage of the appeals process and the State may not await the conclusion of its appeal in order to take corrective action. The State's right to appeal a decision in favor of the enrollee is a right that should be exercised judiciously to target egregious cases and create a uniform policy. As the majority of cases need not be scrutinized for such purposes, the time for corrective action need not be extended. Accordingly, the requirement in Paragraph C(16)(c) to take corrective action within five (5) days of a decision in favor of an enrollee shall not be modified;

(xvi) Defendants' Request (p) to modify Paragraph C(16) regarding the time limitations for filing and resolving medical appeals and Paragraph B(14) setting forth the standard for expedited appeals is **GRANTED in part** and **DENIED in part**.

(1) The State may modify the time limitations in Paragraph C(16) to ensure sufficient time to obtain the enrollees' medical records. Notwithstanding this ruling, the State may not modify the time limitations to exceed the requirements of 42 C.F.R. § 431.244(f). The State, upon consultation with the other parties to this action, shall submit its proposal for approval of such modification to this Court at a time to be determined by this Court subsequent to the issuance of the Memorandum Order.

(2) The State may not modify Paragraph B(14) setting forth the standard for expedited appeals. Notwithstanding this ruling, the State may revise Section 7 of the appeals form to delete the question "**Is a fast appeal** needed because the care is needed right away?" and replace it with "Is this an emergency?" or such other question the State, upon consultation with the parties, deems appropriate. The Court recommends that the State include in its instructions to

the appeals form examples of time-sensitive care and non-time-sensitive care to further guide the enrollee as to what constitutes an emergency. The Court also recommends that the State consider Plaintiffs' suggestion for the development of guidelines identifying time-sensitive and non-time-sensitive care, as explained in Plaintiffs' Response to Defendants' Issues for Clarification (Doc. No. 1250). Without such guidelines, the State itself may not apply the prudent layperson standard to an enrollee's request for expedition and deny the request when it deems the standard is not satisfied;

(xvii) Defendants' Request (q) regarding remedying any defect in a required notice or statement of reasons or legal authorities, as well as its clarification to remedy a missed appeal deadline is **GRANTED in part**. The State may remedy defective notices or remedy a missed appeal deadline in the early stages of an appeal. Remedying a defective notice or missed deadline at a later stage in an appeal raises the risk of delaying the appeals process in violation of 42 C.F.R. § 431.244(f);

(xviii) Defendants' Request (r) regarding their ability to evaluate claims for service in accordance with the definition of medical necessity established by State law (including regulations issued pursuant to the promulgating statute) is **GRANTED**. Paragraphs C(4) and C(7) (as revised by subparagraph (xii) of this Order) of the 2003 Revised Consent Decree (Modified) are not inconsistent with the definition of medical necessity, as they both require the State to consider the enrollees medical records and make an individualized decision;

(xix) Defendants' Request (s) regarding reasonable geographical and/or clinical hardship criteria to determine transfers between MCCs outside of defined open enrollment

periods is **GRANTED** subject to paragraph D(4) of the 2003 Revised Consent Decree (Modified);

(xx) Defendants' Request (t) regarding termination of the 2003 Revised Consent Decree (Modified) is **DENIED**.

This ruling will be followed by a Memorandum Order explaining the Court's reasoning.

It is so ORDERED.

Entered this the 3rd day of August, 2005.

JOHN T. NIXON, SENIOR JUDGE
UNITED STATES DISTRICT COURT